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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,875	09/16/2003	Shi-Lung Lin	89188.0050	3099

26021 7590 03/11/2008

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
03/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,875	LIN ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *13-18 and 21-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-8, 11 and 19 and SEQ ID Nos. 2, and specific donor, acceptor and branch site sequences, in the reply filed on 1/22/2007 is acknowledged. The traversal is on the ground(s) that Groups I and III and II and IV are closely related and there would not be a serious burden on the Examiner to search both groups. Applicant further argues there is no serious search burden to search the related sequences of splice donor and splice acceptor sites because they are all related. This is not found persuasive because with regard to Groups I and III, a search for an isolated RNA would not necessarily reveal an animal comprising the isolated RNA of Group I. Further with respect to the restriction requirement of sequences, each of the sequences comprise different arrangements of nucleic acids and a search for one configuration would not necessarily reveal art for a different configuration. Therefore the sequences are considered unique and different inventions. Applicant's attention is directed to the Notice published in the Official Gazette (1316 OG 122) which as of February 22, 2007supersedes MPEP 803.04. The announcement states in part:

> "The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications.
>
> For National applications filed under 35 U.S.C. 111(a), polynucleotide inventions will be considered for restriction, rejoinder and examination practice in accordance with the standards

set forth in MPEP Chapter 800 (except for MPEP 803.04 which is superceded by this Notice). Claims to polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule.

For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention determination will be made in view of PCT Rule 13.2, 37 CFR 1.475 and Chapter 10 of the ISPE Guidelines. Unity of invention will exist when the polynucleotide molecules, as claimed, share a general inventive concept, i.e., share a technical feature which makes a contribution over the prior art."

With regard to claims 9, 10, 12, 16 and 20 of Groups II and IV Applicant's arguments are the same as for the traversal of Group I and III and for the reasons stated after, each group is a distinct invention. Additionally, after further consideration, claims 9, 10, 12, and 20 read on the elected invention and will be examined along with the elected invention. It appears the Examiner inadvertently included claim 16 in Group II, however claim 16 was properly grouped with Group IV and the restriction requirement still applies for claim 16 for the reasons of restricting Group IV.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Application

Claims 1-57 are pending. Claims 1-12 and 19-20 are currently under examination. Claims 13-18 and 21-57 and non-elected subject matter are withdrawn as being drawn to a non-elected invention.

Information Disclosure Statement

The submission of the Information Disclosure Statement on 07/27/2004 is in compliance with 37 CFR 19.7. The information disclosure statement has been considered by the examiner and signed copies have been placed in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7-12 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell, L. (US Patent No. 6,013,487).

The instant claims are drawn to an isolated RNA or DNA template for an isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene wherein the isolated RNA contains a polypyrimidine tract having SEQ ID No. 2, contains an acceptor site as recited in claim 5 and drawn to a cultivated cell and a composition comprising said isolated RNA.

It must be noted that for purposes of prior art, the claims are interpreted by their broadest reasonable interpretation and as such claim 1 drawn to an isolated RNA comprising an intron RNA that is released in a cell, thereby modulating the function of a target gene is interpreted to mean the isolated RNA, which comprises an intron RNA, modulates the function of a gene. The claims are not limited to the intron RNA modulating the function of a target gene because as recited, the isolated RNA only needs to comprise an intron RNA.

Mitchell teach a DNA template for an RNA wherein the RNA comprises an intron sequence and further comprises a polypyrmidine tract sequence that includes the requirements of SEQ ID No. 2 (see column 12, lines 1-36). Mitchell teach the DNA

sequence further comprises an acceptor site having the sequence of CCACAGC (see column 12, lines 15-20). Mitchell teach the DNA in a vector can be transfected into cultured lung cancer cells using lipofectamine wherein the DNA is capable of transcribing an RNA comprising the intron and wherein the RNA is capable of killing the cells i.e. modulating of a target gene in the cells such that the cells are killed. The instant specification on page 8 defines an isolated RNA as RNA that can be produced from a DNA template in vitro, therefore the DNA template transcribing the RNA taught Mitchell meets the limitations of the instant claims. Further, the instant specification does not specifically define a composition, so for purposes of prior art, a composition is any reagent containing the DNA template or isolated RNA that is capable of being formulated for delivery to cells and as such, the DNA template in lipofectamine taught by Mitchell meets the limitations of the instant claims.

Thus, Mitchell anticipates claims 1-3, 5, 7-12 and 19-20 of the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell, L. (US Patent No. 6,013,487), Krawczak et al. (Hum Genet 1992, Vol. 90: 41-54) and Zhuang et al. (PNAS Vol. 86: 2752-2756).

The instant claims are drawn to an isolated RNA or DNA template for an isolated RNA comprising an intron RNA that is released in a cell thereby modulating the function of a target gene wherein the isolated RNA contains a polypyrimidine tract having SEQ ID No. 2, contains a donor site as recited in claim 4, contains an acceptor site as recited in claim 5, contains a branch site as recited in claim 6 and drawn to a cultivated cell and a composition comprising said isolated RNA.

It must be noted that for purposes of prior art, the claims are interpreted by their broadest reasonable interpretation and as such claim 1 drawn to an isolated RNA comprising an intron RNA that is released in a cell, thereby modulating the function of a target gene is interpreted to mean the isolated RNA, which comprises an intron RNA, modulates the function of a gene. The claims are not limited to the intron RNA modulating the function of a target gene because as recited, the isolated RNA only needs to comprise an intron RNA.

Mitchell is relied upon as above. Mitchell does not teach an isolated RNA comprising a donor site as recited in claim 4 and or comprising a branch site as recited in claim 6.

Krawczak et al. teach a 5' splice donor site having a sequence that contains AAGTAAGT (see page 41).

Zhuang et al. teach a preferred branch site sequence for mammalian mRNA splicing having the sequence UACUAAC (see page 2752).

It would have been obvious to incorporate the 5' donor splice site taught by Krawczak et al. and the branch site sequence taught by Zhuang et al. into the DNA template or isolated RNA comprising an intron RNA taught by Mitchell.

One of skill in the art would have been motivated to use the 5' donor splice site because Krawczak et al. teach the efficiency of splicing is critically dependent upon the accuracy of cleavage and rejoining and given this splice donor sequence has been identified as a consensus sequence for splicing, one would have wanted to use the most effective sequence for accurate splicing activity. One of skill in the art would have been further motivated to use the branch site sequence taught by Zhuang et al. because Zhuang et al. demonstrated that this sequence is preferred in mammalian cells for accurate splicing of mRNA sequence.

Finally, one would have expected to be able to incorporate the sequences taught by Krawczak et al. and Zhuang et al. into the DNA template for the isolated RNA given both demonstrate that each sequence is capable of mRNA splicing and further teach said sequence is the preferred sequence for accurate splicing of mRNA in cells.

Thus in the absence of evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Examiner
Art Unit 1635